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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,789	09/10/2003	Christopher J. Stenland	B185 1210.1 (MSC 8015)	5573

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EXAMINER	
HORNING, MICHELLE S	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/659,789	STENLAND ET AL.	
	Examiner	Art Unit	
	MICHELLE HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *19-22 and 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18, 23-32, 32-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to communication filed 2/3/2009. Claims 1-18, 23-30 and 32-36 are under current examination and claims 20-22 and 31 are drawn to non-elected inventions and are withdrawn. Any previous rejection not reiterated herein has been withdrawn due to claim amendments.

Claim Rejections - 35 USC § 103-MAINTAINED

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18, 23-30 and 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook (US Patent 6730230), Gun'ko et al (Journal of Colloid and Interface Science, 1997) and Schmerr (US Patent 6150172) for reasons of records as set forth in the previous action mailed 9/3/2008.

Response to Arguments

Applicant's arguments filed 2/3/2009 have been fully considered but they are not persuasive. Applicant argues that the Office fails to provide any "rational underpinning" given that Cook teaches a method using specific reactants which appear to teach away from use of material operating on a more general principle (Remarks, p. 10-11). Applicant submits that Cook teaches a specific reactant/target pathogen complex in contrast to the teachings of Gun'ko which provides that fumed silica in aqueous suspensions possesses high adsorption ability for proteins. Applicant contends that the choice of any teaching in Cook for any proposed combination with any teaching of Gun'ko would be considered random and arbitrary by one of ordinary skill in the art.

In response, Cook teaches the method steps of specifically removing prions from solution and the teachings of Gun'ko were applied in that they teach that fumed silica, a fumed metal oxide, has high protein absorption. It is noted that the claimed method is drawn to a resulting solution wherein pathogenic prion proteins *possibly* contaminating the biological material are substantially *reduced* and this may be achieved by either a specific removal as taught by Cook or a removal using a fumed silica in that this metal oxide has an adsorption for proteins in general. While Applicant notes the difference in specificity of the applied teachings, no specificity of pathogenic prion is claimed and such limitations cannot be read into the claims. Given the high adsorption properties of fumed silica is taught by the prior art (see Gun'ko), this rejection is maintained.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that

any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant's arguments do not comply with 37 CFR 1.111(c) because they do not clearly point out the patentable novelty which he or she thinks the claims present in view of the state of the art disclosed by the references cited or the objections made. Further, they do not show how the amendments avoid such references or objections.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the ordinary artisan would have been motivated to use fumed silica given they possess a high protein adsorption ability in combination with the teachings of Cook. This would lead to a solution in which proteins of any type would be reduced, including pathogenic proteins of any type such as prions. Separately noted, Gun'ko provides that fumed silica do not

lose protein adsorption ability during a long period in which the particles remain as microscaled agglomerates (see abstract).

New and/or Reinstated Rejection(s)

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Condie (US 3,998,946).

Condie discloses a method of preparing a solution containing biological material comprising adding fumed silica (which is a fumed metal oxide as claimed) to blood plasma (a biological material) to obtain a solution (e.g., the aqueous blood plasma) comprising a mixture of the fumed silica and the biological material, see abstract and claim 1. Condie further discloses the step of separating the fumed silica from the mixture to form a resulting solution (e.g., the remaining plasma product), see claim 1. This disclosure meets all the limitations of claim 1, since it discloses all the active steps set forth therein. Note, the wherein limitation is not limiting to the detection of prions in

the sample because, first the wherein clause contains no active steps and second, it only requires “prion proteins *possibly* contaminating” the sample. The Condie disclosure also meets all the limitations of claims 32-34, since these claims contain no active steps in the body of the claims that actual separate the prions, or require that the sample contains prions. Since Condie discloses all the active steps set forth in claims 1 and 32-34, it would be expected to be capable of performing the same method.

Claims 1-8, 12, 15-18, 29-30 and 32-36 are rejected under 35 U.S.C. 102(a, e) as being anticipated by Carbonell (US 2005/0014196, relying on provisional filing date of 4/4/2003).

Carbonell et al discloses an invention that relates to prion protein binding, materials which binds these proteins and methods of using these materials in order to detect or remove prions from biological samples (see Title and Introduction). Such removal of prion protein is "essential when the biological fluid is transmitted to another animal or human, such as in a blood transfusion or the administration of a blood product such as a clotting factor" (paragraph 12). More specifically, this reference discloses using inorganic materials as prion binding materials, including aluminum oxide and fumed silica (see paragraph 41). Paragraph 24 defines the term "blood-derived compositions" to include whole blood, red blood cell concentrate, plasma, serum, platelet rich and platelet poor fractions, platelet concentrates, white blood cells, blood plasma precipitates, blood plasma fractionation precipitates and supernatants, immunoglobulin preparations including IgA, IgE, IgG and IgM, purified coagulation factor

concentrates, fibrinogen concentrate, plasma fractionation intermediate, albumin preparation, or various other substances which are derived from human or animal blood.

Carbonell et al make the following recitation in paragraph 63: "The binding material is allowed to contact a sample, such as a biological fluid, under conditions sufficient to cause formation of a prion -binding material complex, and prion protein in the sample binds to the binding material. The binding material is then separated from the sample, thereby removing the prion protein bound to the ligand from the sample. " Example 4 reveals the Western Blot procedures used for the assessment of recovered or depleted infectious and non-infectious prion proteins from solutions of brain homogenates spiked into red blood cell concentrates. The immunodetection of prion proteins was carried out by using specific primary mouse monoclonal antibodies specific to prion proteins (see paragraphs 137-149).

Further, regarding separating the binding material from the mixture, Carbonell et al discloses the following recitation in paragraph 39:"The binding materials provided herein bind to peptides or polypeptides derived from the prion protein, or the entire prion molecule and can be used in a variety of separation processes, including but not limited to, chromatography, such as, but not limited to, thin-layer, column and batch chromatography; solid support and membrane separation; reactor separation; magnetic separation; immunoseparation; and colloidal separation. In one preferred embodiment, the binding materials are contained in a column such as a chromatography column, and a sample is introduced into and allowed to pass through the column so that prion

proteins in the sample bind to the binding materials and are retained on the column. The other components of the sample pass through the column and may be collected. It is to be understood that use of the binding materials described herein is not limited to batch or column chromatography. A variety of configurations, modifications and variations of the use of the binding materials for binding prion proteins are envisioned and fall within the scope of the present invention. Such variations and modifications include, but are not limited to: batch processes; continuous processes; moving bed chromatography processes; low, medium, or high pressure processes; or small, medium or large scale processes. In alternative embodiments, the binding materials are on a membrane, fiber, bead, impregnated into a non-woven mesh, coating a fiber, contained within a filter housing, and the like." With the above recitation, the limitation of filtration is met as well as using a solid substrate as the binding material. Thus, Carbonell et al meet all of the limitations of the claim rejected above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were madeabsentany evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56'to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18, 23-30 and 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carbonell et al. (US 2005/0014196, relying on provisional filing date of 4/4/2003) in view of Condie (US 3,998,946).

Carbonell et al. has been discussed above.

Carbonell fails to specifically discuss surface areas of fumed silica, amounts of fumed silica to use or retention of particles based on specific size exclusions, etc. However, these properties appear to be inherent properties of the specific fumed silica used in the instant invention, e.g., Cab-o-sil.

Condie discloses a method of preparing a solution containing biological material comprising adding fumed silica (which is a fumed metal oxide as claimed) to blood plasma (a biological material) to obtain a solution, as discussed above. Condie specifically discloses the use of Cab-o-sil, see col. 4, lines 56-65.

It would have been obvious to one of ordinary skill in the art to employ Cab-o-sil as the fumed silica in the invention of Carbonell because Condie teaches that this

commercially available fumed silica is useful for methods of separating biological materials. The use of Cab-o-sil would be expected to have the same functional properties as claimed, since this appears to be the fumed silica used, as seen by the instant specification. In the alternative, it would have been obvious to one of ordinary skill in the art to optimize the properties of the fumed silica of the desired surface area since this would to provide the result effective parameter of optimizing the amount of material (e.g., prion proteins, etc.) in which the particles of fumed silica would bind, as surface area of the fumed silica particles would be expected to correlate with binding thereof.

Response to Amendment

The declaration filed on 3/19/2008 under 37 CFR 1.131 has been considered but is ineffective to overcome the Carbonell (US 2005/0014196, relying on provisional filing date of 4/4/2003) reference.

The 1.131 affidavit is deficient for several reasons.

The evidence is insufficient to establish a reduction to practice of the invention in this country or a NAFTA or WTO member country prior to the effective date of the reference. The declaration fails to establish where the alleged reduction to practice took place. While applicant has provided notebook pages as evidence of conception, diligence and reduction to practice; these pages are not clear on their face. It is unclear what samples were used in the experiments, thus it is unclear if the alleged reduction to practice is sufficient to antedate the specific disclosure of the hamster sample set forth in the prior art. The instant claims are broad and drawn to any biological sample. To antedate a

prior art reference, declarant must show that they predated the disclosure of the prior art in order to swear behind a reference disclosing a specific embodiment encompassed by the claims. Applicant has the burden to explain the contents of the pages as proof of acts amounting to conception, diligence and reduction to practice. See In re Borkowski and Van Venrooy 184 USPQ 29 (CCPA 1974). However, this document, nor the laboratory notebook pages do not provide for the conception, diligence and reduction to practice for the breadth/scope of the claimed methods to specifically antedate what is disclosed in the prior art. There are no specifics in the provided notebook pages as to what samples were used or even if prion protein was separated. In fact, the notebook pages only raise a question, e.g., "These results raise the question: Does Prp selectively bind..." (page 2 of notebook pages). Thus, the declaration with the notebook pages fails to specifically establish conception with reasonable diligence and/or reduction to practice. Not only should the declaration provide the experiments performed, but as well as the details of the experiments should be recited. The declarant may not merely point to documentary exhibits attached to the declaration as establishing that the applicant completed the invention prior to the reference date. It is the responsibility of the declarant to clearly explain the documentary exhibits and indicate that these exhibits are intended. The declarant has provided no explanation of the exhibits or how they antedate the specific embodiment of the prior art.

Lastly noted is that the declaration fails to provide signatures of all of the inventors and no petition under 37 CFR 1.183 requesting waiver was filed. See MPEP 715.04.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michelle Horning/
Examiner, Art Unit 1648

/Gary B. Nickol /
Supervisory Patent Examiner, Art Unit 1646